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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,466	04/26/2001	Hiroyasu Kokubo	35576/233803	8005

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,466

Applicant(s)

KOKUBO ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Receipt of the Response and Applicant's Arguments/Remarks, filed 12/10/04 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending. No amendments to the claims have been made. Claims 1-5, 10, 12 and 21-30 have previously been cancelled. Claims 6-9, 11, 13-20 and 31-47 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-9, 11, 13-17 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270).

Hampton *et al.* teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

The multiple characteristic tablet comprises different color sections, which includes a color demarcation line (22) extending transversely between the halves (14 & 18) of the core. The core (12) is preferably coated with a clear material (24). The coloring agents employed are conventional and any desired color combination can be employed (col. 3, lines 5-38).

A feature of the invention is to coat the bi-layer, two-colored tablet with a single coating of gelatin or a film-forming polymeric substance, which will simulate the appearance, and function of the gelatin capsule. Suitable film-forming materials include methylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, ethylcellulose, various derivatives of methacrylic acids and methacrylic acid esters, and cellulose acetate phthalate (col. 5, lines 37-49). The coating of the film-forming polymer may be applied in several ways, such as by using conventional coating pans. Spray guns or other suitable atomizing equipment may be introduced into the coating pans to provide spray patterns conducive to rapid and uniform coverage of the tablet bed. The coating material is sprayed until the tablets are uniformly coated to the desired thickness and desired appearance of the tablet (col. 5, line 59 – col. 6, line 15).

The examples at columns 7-9 demonstrate two-colored, bi-layered capsule-shaped tablets. For instance, Example 1 demonstrates a bi-layered capsule-shaped tablet made from two separate layers, which were compressed together on a tablet press to form a tablet with an appearance similar to a capsule's appearance.

Instant claims are drawn to a solid preparation coated with a continuous film prepared by coating a solid preparation with a continuous film-coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second

part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents. The tablet of Hampton *et al.* is a multi-colored product having two layers wherein distinct colors with different color sections are provided for easy recognition of the tablet. The instant claims are product claims and it is the patentability of the product that must be established. There is no criticality observed in the process of forming the distinct coloration solid preparation, since the end result is a solid product having one or more different colors. As delineated above, the prior art explicitly teaches a tablet formulation having more than one distinct color on the tablet.

Claims 18-20 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) as applied to claims 6-9, 11, 13-17 and 31-44 above, and further in view of Hoover *et al.* (US Pat. No. 5,464,631).

Hampton *et al.* ('270), as discussed above, teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

Hampton *et al.* teach color demarcation lines on the tablet. Hampton *et al.* do not teach the inclusion of patterns comprising logos, bar codes or letters.

Hoover *et al.* ('631) teach a two-colored medicament dosage form having embossed or debossed letters, logos, symbols and the like on the surface of the dosage form (see reference column 4, lines 37-44).

It would have been obvious to use the combined teachings of Hoover *et al.*, who teaches a two-colored medicament comprising embossed letters, logos, symbols and the like, within the formulation of Hampton *et al.* who teaches a two-colored tablet with distinct color demarcations because Hoover *et al.* teach that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form. The expected result would be a distinct, visually improved solid dosage form for easier brand recognition.

Response to Arguments

Applicant's arguments filed 12/10/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the claim objections for claims 6, 7, 11 and 13-17 stating that, "Canceling and re-entering a large number of dependent claims would cause undue confusion and that the objection be withdrawn and renumbering be postponed until allowance".

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Applicant's arguments were persuasive. Accordingly, the claim objections for claims 6, 7, 11 and 13-17 have been withdrawn.

Secondly, Applicant argued regarding the new matter rejection for claims 33-47, which recites in claim 33 the step of 'changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer *to the exclusion of the remainder of the coating*', stating, "The language is merely a characterization of the inherent function of the invention". Applicant's arguments were persuasive. Accordingly, the new matter rejections for claims 33-47 have been withdrawn.

Thirdly, Applicant argued in regards to the 35 U.S.C. §103(a) rejection of claims 6-9, 11, 13-17 and 31-44 over Hampton et al. (US '270) stating, "Hampton does not disclose or suggest the multi-colored continuous film coating layer as recited in independent claims 31 and 33. In Hampton, the coloring agents are contained in the first and second powders used to make the body of the tablet rather than in a coating layer. Hampton's specific description of a clear coating layer teaches away from the recited multi-colored coating layer. Criticality of the claimed coating layer is exhibited by the fact that the coloration of the recited coating layer is distinct from the underlying body of the preparation. The claimed preparation does not require the use of differently colored powders, as does Hampton. The coloration of the Hampton tablet is not changeable after application of the clear coating. Still further, having the coloration within the coating layer rather than the body of the preparation allows intricate patterns, such as bar codes, to be easily created within the coating. Hampton fails to provide a viable method of producing such intricate coloration patterns. The disclosure of Hoover fails to cure the deficiencies of Hampton. Hoover provides no disclosure or suggestion of the recited multi-

colored continuous film layer. Thus, Hoover considered alone or in combination with Hampton, fails to disclose or suggest the claimed preparation.”

Applicant’s arguments have been thoroughly considered, but were not found to be persuasive. The argument that ‘In Hampton, the coloring agents are contained in the first and second powders used to make the body of the tablet rather than in a coating layer’ is not persuasive since a product is being claimed and therefore, it is the patentability of the product that must be established. No criticality has been observed in the use of a coating having different colors. Moreover, no criticality is observed in the radiation steps claimed by Applicants, since the radiation steps do not impart any additional properties to the product being claimed. The Examiner points out, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the tablet of Hampton et al. is a multi-colored product having two layers wherein distinct colors with different color sections are provided for easy recognition of the tablet. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with

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evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). Burden is shifted to Applicant to establish some criticality in the claimed preparation. The prior art teaches and suggests tablets comprising more than one distinct color, albeit in the body of the tablet. Applicant's argument that 'the disclosure of Hoover fails to cure the deficiencies of Hampton and that Hoover provides no disclosure or suggestion of the recited multi-colored continuous film layer' is not persuasive since Applicant's have not demonstrated any unusual or unexpected results that accrue from the instant film coating layer recited. The prior art formulations nevertheless, teach tablets having multi-colored arrangements. Hoover et al. was cited for their teaching that it is known in the art to employ patterns that include logos, bar codes or letters in multi-colored tablet formulations. According to Hoover, the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form (see Hoover col. 4, lines 37-43). It is the position of the Examiner that the presence of logos in a solid preparation would provide for different color intensities on the surface of the preparation and thus would also meet Applicant's desired properties. The prior art recognizes tablet formulations having more than one distinct color on the tablet. Thus, the instant invention is rendered *prima facie* obvious over the cited art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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February 28, 2005


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